K070344

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

Ulli Haslacher
President
Liv International USA, Inc.
2335 West Foothill Blvd., Suite 14 and 15, Upland, CA 91784

Phone: (909) 931-1719
Fax: (909) 931-1947

Email: ulli@livinternational.com

MAR 0 8 2007

Date prepared: 5 January 2007

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name

Liv™ Breast Self Examination Aid

Proprietary Name

Liv™ Breast Self Examination Aid

Classification Names

Mammographic X-ray system (892.1710; IZH, regulatory class II)

3) Identification of the predicate or legally marketed device:

Liv International USA, Inc. believes that the Liv™ Breast Self Examination Aid is substantially equivalent to the previously cleared My Breast Friend device from MBF Sales, LLC (Rockville, MD). The predicate 510(k) number is K023390.

4) Device Description:

The Liv™ Breast Self Examination Aid is indicated as an aid for performing breast-self examinations. The device is made of soft, latex-free polyurethane and filled with a non-toxic lubricant. While allowing the breast tissue to remain in place during an exam, your fingers can still move effortlessly across the breast while detecting abnormalities.

The Liv™ Breast Self Examination Aid is designed to comply with the standards listed below:

- *Premarket Notification 510(k): Regulatory Requirements for Medical Devices*, HHS Publication FDA 95-4158 (1995).
- ISO14971 *Medical devices- application of risk management to medical devices* (2000).

The Liv™ Breast Self Examination Aid will be cleared and/or approved by the following agencies:

- U.S. Food and Drug Administration (FDA)
- European Medical Device Directive (MDD)- 93/42/EEC Notified Body

5) Intended Use:

The Liv™ Breast Self Examination Aid is indicated as an aid for performing breast-self examinations.

6) Performance Standards:

Liv International USA, Inc. is not aware of any special controls or performance standards established for this device under sections 513 or 514 of the Food, Drug and Cosmetic Act.

7) Conclusion Statements:

In summary, the Liv™ Breast Self Examination Aid meets or exceeds all safety requirements for a device in its regulatory class and is found to be identical in materials and functionality when compared to the stated predicate device.

510(k) Summary/Statement Certification

Re: K 070344 ~~(not yet assigned)~~

CHECK ONLY ONE:

X 1. **510(k) Summary**. Attached is a summary of safety and effectiveness information upon which an equivalence determination could be based.

o 2. **510(k) Statement**. I certify that, in my capacity as President of Liv International USA, Inc., I will make available all information in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, as defined in 21 CFR 20.61.

[Signature*]

Ulli Haslacher

[Typed or Printed Name]

January 15, 2007

[Date]

* Must be signed by a responsible person of the firm required to submit the pre-market notification (e.g., not a consultant for the 510(k) submitter).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 0 8 2007

Liv International USA, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, N.W.
BUFFALO MN 55313

Re: K070344
Trade/Device Name: Liv™ Breast Self Examination Aid
Regulation Number: 21 CFR §892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: February 5, 2007
Received: February 6, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~TBD~~ K070344

Device Name: Liv™ Breast Self Examination Aid

Indications For Use:

The Liv™ Breast Self Examination Aid is indicated as an aid for performing breast-self examinations.

Prescription Use _____ AND/OR Over-The-Counter Use _X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070344